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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,698	09/26/2001	Francis Barany	19603/3355 (CRF D-1595E)	2018

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 09/08/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,698

Applicant(s)

BARANY ET AL.

Examiner

Padmashri Ponnaluri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 89-119 is/are pending in the application.
- 4a) Of the above claim(s) 98-108 and 113-119 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 89-97, 109, 111 and 112 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other:

DETAILED ACTION

1. Applicant's election of Group I, claims 89-112; and glass as species for solid support, different nucleic acids as species of capture oligonucleotides, carboxyl groups as species to functionalize the solid support, acrylic acid as the species of monomer used in polymerization, O-nitrobenzyloxycarbonyl as species of photoactivatable group, and a barrier oligonucleotides shorter than the capture probes; in Paper No. 9, filed on 6/24/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Applicants along with the election noted that 'all the groups of the invention identified in the office action are closely related and therefore, would require common areas of search and consideration. Applicants arguments have been considered and are not persuasive because group I and group II inventions even though closely related the methods are patentably distinct from each other and the search for group I would not result in finding references for group II (i.e., the references used for group I claim rejections would not be obvious over group II claims). Thus the restriction has been maintained.

3. Claims 113-119 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

4. Claims 98-108 (dependent on claim 99) 110 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

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5. Claims 89-119 are pending in this application and Claims 89-97, 109, 111-112 are currently being examined in this application.

Drawings

6. This application, filed under former 37 CFR 1.60, lacks formal drawings. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings. In unusual circumstances, the formal drawings from the abandoned parent application may be transferred by the grant of a petition under 37 CFR 1.182.

Oath/Declaration

7. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

NOTE that the citizenship, and address of inventor 'Maria Kempe' have been changed without initials.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 89-97, 109, 111-112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 89 recites the limitation "the array of a plurality of capture oligonucleotides" in line 7. There is insufficient antecedent basis for this limitation in the claim.

Claim 89 recites the limitation "the activated array positions" in line 9. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 89-97, 109 and 111-112 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,510,270 (Fodor et al).

The instant claims briefly recite a method of forming arrays of oligonucleotides on a solid support by attaching to the solid support a linker suitable for coupling oligonucleotides, and forming an array of a plurality of capture oligonucleotides by series of cycles of activating selected array positions for attachment of multimer nucleotides.

Fodor et al teach a method for synthesizing and screening oligonucleotides on a solid support. The method provides for the irradiation of a first predefined region of a substrate comprising immobilized nucleotides on its surface, without irradiation of a second predefined region of the substrate. The irradiation step removes a protecting group from the immobilized nucleotides. The substrate is contacted with a first nucleotide to couple the nucleotide to the

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immobilized nucleotides in the first predefined region without coupling in the second predefined region. At least a part of the first predefined region and at least a part of the second predefined region are subjected to further irradiation. The substrate is contacted with a second nucleotide, which couples to the immobilized nucleotides in at least part of the first and at least part of the second predefined regions. By repeating these steps, an array of diverse oligonucleotides is formed on the substrate (refers to the instant claimed method) (i.e., see abstract).

Fodor et al teach the solid support is substantially flat and may have wells, raised regions, etched trenches, or the like (i.e., see column 7, under substrate or in column 11) (refers to instant claims 94). Fodor et al teach that the substrate surface is composed of inorganic glass (i.e., see column 11) (refers to instant claims 91-92). Fodor et al teach that the substrate is conventional microscope slide or coverslip (i.e., see column 16) (refers to instant claim 92).

Fodor et al teach the use of 'nitrobenzyloxy carbonyl' as the protecting group (i.e., see column 7) (refers to instant claim 106). Fodor et al teach that the surface of the substrate contains reactive groups which can be carboxyl, amino, hydroxyl (refers to instant claim 97) (i.e., see column 11).

Fodor et al teach that the any conceivable substrate may be employed in the invention. The substrate may be in the form a sheet, tubing spheres, plates, films, and the any convenient shape such as disc, square, sphere, sphere, circular, and the substrate may contain raised or depressed regions on which the synthesis takes place (refers to instant claim 95) (i.e., see column 11).

Fodor et al teach that the substrate is polymerized with gels or polymers such as (poly)tetrafluoroethylene, (poly)vinylidenedifluoride, polystyrene, polycarbonate (refers to instant claim 104) (i.e., see column 11).

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Fodor et al use a mask to illuminate(or irradiate) selected regions of the substrate and uses photolithographic technique in synthesis of polymer arrays. Fodor et al teach that a square area is divided into square boxes, and the first reactions are carried out in the vertical columns and the process is repeated in the horizontal direction for the second unit of dimmer (i.e., see columns 18-19) (refers to instant claim 90). Fodor et al teach that one mask can be used in all eight steps if it is suitably rotated and translated. For example, a mask with a single transparent region could be sequentially used to expose each of the vertical columns, translated 90° and then sequentially used to allow exposure of the horizontal rows. Fodor et al teach that by controlling the locations of the substrate exposed to light and the reagents exposed to the substrate following exposure the locations of each sequence will be known (i.e., see column 9). Thus the reference clearly anticipates the claimed invention.

12. Claims 89-94, 96-97, 109, 111-112 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,527,681 (HOLMES).

Holmes et al teach a synthetic strategy for the creation of large scale chemical diversity using solid phase chemistry, photo labile protecting groups and photolithography achieve light directed spatially addressable parallel chemical synthesis of an array of polymers (i.e., see abstract). Holmes teaches that the preferred embodiment provides for the synthesis of an array of polymers in which individual monomers in a lead polymer are systematically substituted with monomers from one or more basis sets of monomers. The reference teaches that the substrate is flat and it may have synthesis regions separated by structures, and the surface may have wells, raised regions, or etched trenches (i.e., see column 5). The reference teaches that the substrate has linker molecules which are optionally protected with photo removable protecting groups.

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The reference teaches that the mask is used and rotated for the following coupling steps. The reference claims and specification disclosure are drawn to a method of synthesizing an array of oligonucleotides on a surface of a substrate clearly anticipates the claimed invention.

13. Claims 89, 93 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al (BioTechniques, Vol 19, No. 3, 1995, pages 442-447).

Lipshutz et al teach high density oligonucleotide arrays created using light directed chemical synthesis. Light-directed chemical synthesis combines semiconductor based photolithography and solid phase chemical synthesis. The reference teaches linkers modified with photochemically removable protecting groups are attached to a solid substrate. Light is directed through a photolithographic mask to specific areas of the synthesis surface, activating those areas for chemical coupling. The first of a series of nucleoside harboring a photolabile protecting group at the 5' end is incubated with the array, and chemical coupling occurs at those sites that have been illuminated in the preceding step, next light is directed to a different region of the substrate through a new mask, and the chemical cycle is repeated. Using the proper sequence of masks and chemical steps, a defined collection of oligonucleotides can be constructed, each in a predefined position on the surface of the array. The reference clearly anticipates the claimed invention.

14. Claims 89 and 93 are rejected under 35 U.S.C. 102(b) as being anticipated by Fodor et al (Nature, vol. 364, August 1993, pages 555-556).

Fodor et al teach a method of preparing miniature biological arrays using light directed combinatorial chemical synthesis of biopolymers on a solid support. Fodor et al teach light directed chemical synthesis employs semiconductor based photolithography and solid phase

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14. Claims 89 and 93 are rejected under 35 U.S.C. 102(b) as being anticipated by Fodor et al (Nature, vol. 364, August 1993, pages 555-556).

Fodor et al teach a method of preparing miniature biological arrays using light directed combinatorial chemical synthesis of biopolymers on a solid support. Fodor et al teach light directed chemical synthesis employs semiconductor based photolithography and solid phase chemical synthesis. Synthesis linkers modified with photo chemically removable protecting groups are attached to a solid support, light is directed through a photolithographic mask to specific areas of the synthesis surface effecting localized photodeprotection. The first of series of chemical building blocks is incubated with the surface and chemical coupling occurs at those sites which have been illuminated in the preceding step. Next the light is directed to a different region of the substrate through a new mask, and the chemical cycle is repeated. The reference clearly anticipates the claimed invention.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 703-305-3884. The examiner is on Flex Schedule and can normally be reached on Monday through Friday between 7.30 AM and 3.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

Pp
5 September 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER